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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/330,544	06/11/1999	ROBERT F. BAUGH	17720-059	9553

7590

07/30/2003

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EXAMINER

ALEXANDER, LYLE

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,664

Applicant(s)

HERPST, ROBERT D.

Examiner

Lyle A Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6, 8, 10-12, 14, 16, 18-22, 24 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6, 8, 10-12, 14, 16, 18-22, 24 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6,8,10-12,14,16,18-22,24 and 26-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have added the new claim language "wherein all of said plungers are lifted in unison" which does not appear to be supported in the original specification. Applicants specifically stated support for these amendments is found on page 3 lines 29-33 of the original specification where USP 4,599,219 ('219 hereafter) is mentioned as teaching an example of the test cartridge's insertion into the test apparatus. MPEP section 608.01(p) teaches mere reference to another patent is not an incorporation of anything therein into the application containing such a reference for the purposes of the disclosure requirement under 35 USC 112 1st paragraph. In re de Seversky (177 USPQ 144). In the absence of Applicant stating '219 relates to the simultaneous operation of the plungers, it is not clear how one could read this subject matter into the original specification from '219.

Double Patenting

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4-6,8,10-12,14,16,18-22,24 and 26-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-40 of U.S. Patent No. 5,972,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach methods of evaluating the clotting characteristics of blood.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

For the purposes of examination, it will be assumed the limitations to "wherein all of said plungers are lifted in unison" will be considered. The Office is not conceding on the above 35 USC 112 1st paragraph rejection. If the 35 USC 112 1st paragraph rejection cannot be resolved, then the Office will repeat the 12/06/02 final rejection.

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Claims 4-6,8,10-12,14,16,18-22,24 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baugh (USP 5,314,826) in view of Hanahan et al.(USP 4,329,302) together further in view of Cooper et al.

Baugh teaches a methods for the evaluation of clotting characteristics of platelets. A sample is dispensed into a test cell. An activating agent such as kaolin is added. The method also includes reciprocating the plunger to determine the clotting properties of the blood.

Baugh is silent to the claimed "1-O-alkyl... phosphorylcholine" (e.g. AGEPC hereafter) reagent.

Hanahan et al. teach AGEPC is a potent platelet activator. It would have been within the skill of the art to modify Baugh (USP 5,314,826). in view of Hanahan et al.(USP 4,329,302) and use AGEPC to gain the advantage of high platelet activation.

Baugh in view of Hanahan is silent to the claimed concentrations of AGEPC.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. Selection of the optimal concentration of a known reagent having well known properties, such as platelet activation, is a result effective variable.

It would have been within the skill of the art to further modify Baugh and use the AGEPC in the claimed concentrations of 0-2.76 micrograms and/or 0-150nm.

Baugh (USP 5,314,826) in view of Hanahan et al.(USP 4,329,302) is silent to the newly claimed limitation "wherein all of said plungers are lifted in unison". Cooper et al. teach a similar device for determining coagulation parameters of blood. In column 2

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lines 37+ teach it is important to be able to conduct a plurality of tests simultaneously to achieve faster, potentially life saving results.

It would have been within the skill of the art to further modify Baugh (USP 5,314,826) in view of Hanahan et al.(USP 4,329,302) further in view of Cooper et al. to move all of the plungers in unison to gain the above advantages.

Response to Arguments

Applicant's arguments with respect to claims 4-6,8,10-12,14,16,18-22,24 and 26-28 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 703-308-3893. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9319 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.



Lyle A Alexander
Primary Examiner
Art Unit 1743

July 25, 2003